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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/849,343	05/07/2001	Juergen Roemisch	06478.1455	1124

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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER  
LLP  
1300 I STREET, NW  
WASHINGTON, DC 20005

EXAMINER

HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b>	<b>Application No.</b> 09/849,343	<b>Applicant(s)</b> ROEMISCH ET AL.	
	<b>Examiner</b> Phuong Huynh	<b>Art Unit</b> 1644	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 04 August 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☐ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 14-16.

Claim(s) objected to: None.

Claim(s) rejected: 1-9 and 17.

Claim(s) withdrawn from consideration: 10-13.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
10. ☐ Other: \_\_\_\_\_

Continuation of 3. Applicant's reply has overcome the following rejection(s): The objection to the specification for not contain antecedent support for "more than 1.5 g/ml" is hereby withdrawn in view of the support in paragraph 6, lines 1-6 of specification. Further, the rejections of claims 1-6, 8, 14-15 and 17 under 35 USC 103(a) as well as claims 7, 9 and 16 under 35 USC 103(a) are hereby withdrawn in view of the fact that the '940 patent is not prior art and co-owned by Aventis Behring GmbH as evidenced by the attached assignment records.

Continuation of 5. does NOT place the application in condition for allowance because: Applicants' arguments have been fully considered but not found convincing for the same reasons set forth in paper No 10. Applicants argue that claim 1 previously has been amended to recite that the composition comprises "more than 0.5 mol/g of each of two or more amino acids chosen from arginine, lysine, histidine, phenylalanine, tryptophan, tyrosine, aspartic acid and its salts and glutamic acid and its salts; wherein one of said amino acids is glutamate". The '717 composition is limited to "in the range of about 0.05M to about 0.8M". However, the term "about" in the reference expands the reference range to include 1.01 M or 1.01 mol/g of at least one amino acid selected from the group consisting of amino acid such as arginine, lysine, phenylalanine, tryptophan, aspartic acid, glutamic acid and its salt (glutamate) in the reference composition. (see column 5, lines 36-38, in particular). Applicants further argue that unlike in the '717 patent, the claimed compositions in claim 1 require that one of the chosen amino acids must be glutamate. However, the '717 patent also teaches the salt of the aforesaid amino acid, such as glutamate which is the salt of glutamic acid (See column 5, lines 27-28). Thus the teachings of the '717 patent anticipates the claimed invention. On page 8 of the amendment, Applicants argue that the '757 patent does not remedy the deficiency of the '717 patent. One of ordinary skill in the art looking at these two patents, would have no desire to select glutamate as a necessary component in his compositions. Further, Applicants' claims require "two or more" amino acids. The '717 patent suggests no particular advantage in using more than one amino acid. In contrast to Applicants' assertion that the '717 patent does not teach glutamate, the '717 patent teaches the salt of reference glutamic acid, which is glutamate (see column 5, line 27-28, in particular). The claimed "two or more amino acids" is an obvious variation of the references teaching since the '717 patent teaches a mixture of amino acids selected from the group consisting of arginine, lysine, phenylalanine, tryptophan, aspartic acid, glutamic acid and its salt and preferably at least one arginine for stabilized protein preparation against loss of activity during pasteurization (See column 5, lines 5-39 of '717 patent, in particular). The '757 patent teaches that one may use "amino acids" in a stabilized protein preparation to protect against a loss of activity during pasteurization such as glycine and the salt of calcium (CaCl<sub>2</sub>). The motivation to combine can arise from the expectation that the prior art elements will perform their expected functions to achieve their expected results when combined for their common known purpose. Section MPEP 2144.07. For these reasons, the 102 (b) and the first 103(a) rejections remain.



CHRISTINA CHAN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600